

1 ABSTRACT OF THE DISCLOSURE

2 A clear aqueous formulation for topical application in the oral cavity of  
3 humans to treat leukoplakia contains water,  $\beta$ -carotene, a water miscible  
4 polyol, an unsaturated fatty acid ester, and a surfactant, preferably  
5 polyethoxylated castor oil. The formulation preferably also contains a  
6 pharmaceutically acceptable anti-oxidant, preferably d-alpha-tocopherol  
7 (vitamin E), and is in the form of an oral rinse or as a gel well suited for  
8 spreading on gums or other parts of the oral cavity. The formulation is applied  
9 in a gel form on a substantially regular daily basis to areas in the oral cavity  
10 where leukoplakia lesions are present. Persistent application of the gel results  
11 in substantial diminution or total elimination of the leukoplakia lesions.